

Clinical Laboratory Program

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COMMONLY ASKED QUESTIONS ABOUT HIV TESTING

Where can the statute and regulations relating to HIV testing be found?

Response: The statutes regulating HIV testing are M.G.L. 111 § 70F [confidentiality] and M.G.L. 111D [clinical laboratory]

The regulations covering HIV testing are covered by the clinical laboratory regulations 105 CMR 180.000 Rules and Regulations Relating to the Operation, Approval, and Licensing of Laboratories.

The relative sections are: 180.300 - Special Requirements-Viral Serology [HIV testing]
180.180.031 - Special Projects (covers waived HIV testing)

Are the regulations governing non-waived HIV testing different from those for waived HIV testing?

Response: All facilities performing HIV testing are covered by state laboratory regulations. The regulations vary depending on the licensure status of the testing facility.

Facilities licensed by the DPH These facilities must apply for and be licensed/approved for laboratory testing under the Specialty: Immunology with the Subspecialty: Viral Serology.

Facilities not licensed by the DPH performing “Waived” HIV testing These facilities must apply for a special projects waiver from the Clinical Laboratory Program, DPH, in order to perform the waived HIV testing. The waiver requirements have been jointly developed and implemented by the Clinical Laboratory Program and HIV/AIDS Bureau. Examples of facilities qualifying this special projects waiver are: AIDS testing/counseling locations, Planned parenthood locations, correctional facilities.

If a facility only collects specimens for HIV testing and does not perform any testing on-site does the facility need to notify and/or send any documentation to the DPH?

Response: Any facility collecting HIV specimens must use a reference laboratory which is “approved” by the Department. The “approved” laboratory must comply with the regulations and can instruct the facility as to how to collect and transport specimens(e.g., patient identification, consent, etc.). The facility does not need to send any information to the Department.

If a state licensed laboratory accepts HIV specimens from a client (i.e., blood drawn by physicians or blood drawn at a collection station) but does not perform the HIV testing on-site (i.e., forwards the specimens onto an out-of-state reference laboratory) does the laboratory need to comply with the state HIV regulations?

Response: Yes, the accepting laboratory must comply with applicable regulations. Regulations regarding proficiency testing would not apply.

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Does a reference laboratory that tests specimens on-site need to comply with regulations regarding patient consent.

Response: Yes. It is the responsibility of the reference laboratory to develop a consent form. The form should be distributed to the laboratory's clients. The ordering physician, client or account must obtain the consent.

What is meant by patient confidentiality?

Response: M.G.L. 111D S.70F prohibits testing for HIV and disclosing results of an HIV test without the written informed consent of the test subject. A laboratory processing specimens and/or testing specimens for HIV is responsible for limiting access to the patient information and test results. Coding of patient names is not required but should be encouraged. Test results maintained in a locked file cabinet or in the patient's medical record are both acceptable. Some hospital laboratories require that all requests be processed through the infectious disease physician; other hospitals allow any physician to order the test. Both policies are acceptable. .

What laboratories are approved to perform the test or accept specimens for processing?

Response: A current list which is updated periodically is available from the Department.

A facility only performs the test on blood donors. Does this facility need to comply with the regulations?

Response: Yes. The facility needs to apply to the Department for HIV approval.

Why are facilities performing "waived" HIV testing required to meet state regulations that are more stringent than the federal regulations?

Response: Input from several different authorities was gathered before the state regulations were developed. It was the consensus of this group that for the protection of the persons choosing to have the "waived" HIV test performed it was critical that the test be performed correctly. It was determined that even though the test was "waived" by CMS it did not meet the statutory definition of (1) employing methodologies that are so simple as to render the likelihood of erroneous results negligible and (2) of posing no reasonable risk of harm to patients if the test is performed incorrectly. It was also determined to be a test that would routinely be performed by personnel not familiar with, nor had training in, "good laboratory practices" in environments that were not traditional testing venues. All of these facts led to the decision to require testing personnel/facilities to follow laboratory and counseling practices that would provide the best quality care to the clients being served.

Why are two different bureaus involved with the waived HIV testing?

Response: The Department of Public Health, Clinical Laboratory Program is responsible for overseeing the quality of laboratory testing performed within the Commonwealth. The HIV/AIDS Bureau is responsible for overseeing the counseling services provided to HIV patients within the Commonwealth.

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Since the goal of the waived HIV testing is to provide testing at locations that are more readily available to the general public it only made sense for these to Programs to work together - one to oversee the quality of laboratory testing and one to oversee the patient services.